

**MSFC meeting with NQA
March 5-6, 1997**

MSFC Registration Issues

1. Registration Scope
 Quality Planning

MSFC's present scope is acceptable to NQA. We can apply for an extension of scope at a later date. We will easily have the opportunity to have additional areas audited for registration and inclusion in our scope during the same timeframe as our surveillance audits (every 6 months).

Application of our policy must be determinate with respect to each and every element. We can fence out activities/organizations/buildings/projects/functions from our scope as long as we don't misrepresent what we're registered for and as long as we don't fence out serial steps in a process. It is okay to fence out parallel processes and beginning and ending steps in a serial process. We must be able to clearly define the boundaries.

Tailoring of the quality system is allowed; however, the minimum requirements in ISO 9001 must still be met. We can not tailor out any of the minimum requirements, although there is flexibility in how we decide to meet them.

What if our customer says, "I don't want ISO"? Our policy will have stated that we will comply with ISO, so we must. What the customer is willing to pay for is irrelevant to our commitment to comply with at least the minimum requirements of ISO.

R&D was discussed. Proceduralize the process of what is done now. Write procedures as a minimum for this type of effort. Don't identify everything.

Prototype drawings may be identified by stamping them, "prototype."

For R&D: the normal free-form scientific process complies with ISO.

2. On-site Contractor Strategy

MSFC's contractor strategy was discussed with NQA.

NQA will only look at activities within the scope of MSFC's quality system during their assessments.

If a contractor is working to MSFC's processes and procedures, then MSFC is accountable for them.

If the contract states that a contractor must be compliant, the registrar will ask how we determine that they are.

3. Documentation Structure and Control
 External Documents

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"If the system takes me to a document, that's where I go." (NQA)

If an external document is used by MSFC, we are responsible to check with the issuing organization for the latest version. If the customer expects work to the latest revision, then we have to do that. If the customer agreement is to work to a particular revision, we must work to that revision.

Documents rescinded by the issuing agency must be marked, but can be kept for appropriate use.

Agreements to use a specific revision level of a document are okay. The stated revision is the one that should be in use.

Documents such as equipment manuals are uncontrolled documents. They are not controlled by the equipment manufacturers and would not need to be on our master list. The manual version must match the equipment type/model that it is being used for.

4. Documents under Transition during Registration Assessment

Transition documents can be used as long as people understand the documents needed and how to apply them. There should be a plan for transitioning the documents and a target completion date. However, certain critical documents need to be in place, as the registrar is looking for a mature system.

NQA will accept "red-lines" as a process if it is controlled.

5. Grand-fathering Existing Projects

MSFC can state cut off date(s) for the old quality system, transition period, and date to be within the new quality system for long-term programs like shuttle. Programs ending don't have to be transitioned.

Grand-fathering training - must identify that people are grand-fathered by virtue of previous education, training, and/or experience. You don't have to try to go back and document all training for a person from day one.

Grand-fathering subcontractors - subcontractors can be grand-fathered based on prior performance without doing a new survey/evaluation, etc.

6. References to ISO vs. ANSI/ASQC and use of revision date

It is acceptable to state either the European or U.S. standard. Use of the revision date is not necessary. Can state that the current version is used.

7. Quality Records Approach -

Is a single reference list/matrix necessary?

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A single reference list is not necessary. It is up to us how/where we want to indicate what our records are.

What is your interpretation of "readily retrievable"?

NQA is more interested in methodology of retrieving records than in a specific time period. Would prefer to get records requested during the audit timeframe, but have no expectation of a specific time period. Six months would probably be considered unreasonable for the types of records that would be requested. If people understand what the process is and can point in the right direction to find records, and if there is an orderly method, then the time taken is not so important. The problem is when people don't know where to start looking, or if there's situations like a roomful of unlabeled boxes of records.

Caution was given on giving minimum retention time. Our Lead Assessor, for NQA, said that if we state a "minimum of 3 years" for record retention, then it will raise a question if he finds records kept much longer than that as to the validity of the original statement. This would be a finding.

Record retention may be based upon the life of a program, e.g. "6 months past the end of the program."

8. Procedure detail - Is it acceptable to state that an office/lab is responsible for performing an activity or must a specific title or position be called out?

NQA will accept the level of detail that MSFC feels is necessary. If calling out an office works, then that's okay. If that causes confusion or doesn't work, then we must give more detail. It is acceptable to do more training and less procedures or less training and more procedures. It is up to us to determine how to balance this.

9. Level of detail for documenting items reviewed and found compliant during internal audits

1) Sampled 10 out of 50 purchase orders for review and approval - no nonconformances noted.

vs.

2) Sampled 10 out of 50 purchase orders for review and approval - no nonconformances noted. P.O. #'s examined: 123, 456, 789, 321, ..., 987.

vs.

3) (✓) Review and approval of purchase orders
(Check mark indicating acceptable condition on an audit checklist item)

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Both 1 and 2 are okay. Number 2 is the best method to document actual items reviewed. There is better traceability. Number 3 is not sufficient. There is no objective evidence of what, if anything, was looked at.

State in your audit notes if you interviewed people, reviewed records, etc. to reach conclusions. You must include evidence of what you looked at, evidence of what you found, and then after corrective action, that the action was verified (what was looked at again/how verified) and accepted.

Audits can be done any way we'd like as long as the twenty (20) elements are covered across the quality system. The schedule should be based on the criticality of items/elements, and the frequency should be increased if there are problems in specific areas. Any method can be used: tracing, sampling, etc.

10. Level of detail for controlling and documenting On the Job Training

OJT is acceptable for training. If the system is formal, then document that formally. If the system is informal, then less formal documentation would be appropriate. When a new procedure comes out, people must read it and be trained on it. This is OJT and should be documented. Same for new policies that people must be familiar with. Education, job descriptions, performance evaluations, training to the Quality System procedures, and unique job requirements are components of training. Personnel qualifications can be grand-fathered by supervisors putting a statement on file that the person is qualified for the specific job based on X years experience. NQA is most concerned about training to (MSFC) procedures for a particular area/job. You need to be trained to your organization's procedures.

Other Notes

"NQA - the Aerospace Auditor"

NQA has registered government units and design/development organizations, but never a government design/development organization.

Areas that seem to give aerospace companies trouble: 4.1, 4.4, 4.17, and 4.18

Areas that are usually in good shape for aerospace companies: 4.3, 4.13, and 4.14

Executive management must take ownership/responsibility for the ISO system.

Caution on management reviews - management reviews sometimes turn into just a presentation by Quality of charts and metrics. This should be an action meeting with an established quorum of executive management. There should be a review of policy, audits,

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significant problems, customer satisfaction, corrective action, and a conclusion that the system is or is not working. NQA will look for the agenda, minutes and list of attendees, including the attendees' functions.

Calibration contractors must be audited or must have an ISO certificate or some other evidence of traceability to NIST.

On 4.19, Servicing, key issues are based on the customer contract. State in the procedures what is contractually specified. "When contractually specified, MSFC will do this..."

On 4.4, Design Control, will look for minimum compliance - inputs, outputs, change control, validation, verification.

Look at the intent of the ISO 9001 standard and define in the policy and procedures how to meet the intent.

MSFC should not write any document just for auditors. If a document does not make sense to have within our system, it shouldn't exist.

The quality manual should make reference to the system level procedures and outline the documentation structure for the quality system. Work Instructions (Level 3 and 4) are not required by the standard to reference back up to the system level (Level 2) documents.

Use common sense!

Memorandums may be a valid method for giving instruction.

If documents are stated to be controlled electronically, then paper copies are uncontrolled, and people using them are responsible for ensuring that they have the latest version. People will be asked to call up electronic procedures during an audit if those are the stated controlled versions.

There must be a disaster recovery plan for an electronic documentation system.

Change bars are a good method to ensure that employees can readily identify revisions to a procedure. (If finding the changes is too cumbersome, it is more likely that they will not be read.)

Document retraining may be required as a result of corrective action.

Ensure that newly hired employees receive ISO orientation and training over time. We are conducting heavy training now. Six months from now, will there be new people that need the same training?

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Engineers often make the best auditors.

Documentation Review by NQA - NQA will perform a review of the quality manual and system level procedures prior to scheduling a pre-assessment with us. They will spend one day performing this review, and have committed to providing us with their comments within two weeks of receipt of the documents. All of these procedures must be sent at once for the review to be completed. We must supply a matrix of the manual and procedures to the ISO 9001 standard requirements. This review is only to see if the quality manual and system level procedures address all of the requirements in the ISO standard.

Scheduling with NQA - NQA requests two months notice to schedule audit activities. Three weeks prior to the audit the NQA team will be contracted to go, so changes would be a problem.

Pre-Assessment is optional. NQA will perform up to two pre-assessments. They are prohibited from doing more by their accreditation bodies, as doing more would be considered consulting and a conflict of interest. The pre-assessments can be tailored to meet our needs and can be as extensive as an actual registration assessment if we choose.

Areas always covered during pre-assessments, registration assessments, and ongoing surveillance:

1. Corrective and Preventive Action
2. Internal Audits
3. Management Review

In addition to these three, at least three other elements will be chosen at random for surveillance audits every six months. An audit of the entire quality system will not be performed again after the initial registration. Portions of the quality system will be covered during the surveillance audits in a manner such that the entire system has been re-evaluated at least once during a three year period.

Audit findings may fit into any of three categories:

1. Observation - (lowest level) indicates that there is an item to address for potential problems or an item that requires clarification. An observation could lead to a nonconformance.
2. Minor nonconformance - (second level) a violation of our own procedures or of the ISO standard.
3. Major nonconformance - (highest level) a significant gap in the system. A requirement has been completely missed or there are several minor nonconformances that combine to indicate a systemic problem.

NQA uses the ISO standard itself to perform audits. They do not use checklists.

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Prior to the registration assessment, at least one audit/audit cycle of the quality system must be completed, at least one management review must be performed and documented, and there must be objective evidence that the 20 elements have been implemented.

If a major nonconformance is identified during the registration assessment, registration will not be recommended. (A major nonconformance may be a single nonconformance indicating a significant gap in the system, or it may be made up of several minor nonconformances that indicate a systemic problem.) In that event, MSFC will have two options: discontinue the audit and reschedule, or continue on to complete the audit. Another full audit may be required, or just a partial audit of the problem areas.

Registration will be recommended upon NQA's acceptance of any necessary corrective action plans from MSFC for minor nonconformances (no major nonconformances - major nonconformances require re-audit). Corrective actions do not have to be completed and verified prior to registration being recommended. Corrective action follow-up will take place during the first surveillance.

Appeals Process - If MSFC disagrees with the audit findings and cannot resolve the issues with the NQA Lead Assessor, there is an appeals process available. Issues are elevated to the President and Quality Director of NQA, then to an Independent Certification Board (ICB) if there is no resolution with NQA. The ICB decision is final.

Surveillance - The first surveillance audit is conducted three months after the registration assessment, the second one is conducted nine months later (around the initial registration anniversary), and then they are conducted every six months thereafter. The schedule for surveillance may be extended to an annual basis, based on surveillance results.

After registration to ISO 9001 through NQA, if there are any significant changes to the quality system we must notify NQA. We do not have to keep them updated on routine procedure changes.

Promotion of ISO Registration and use of the NQA logo - there are regulations covering use of our registration and NQA's logo. We cannot affix the logo physically to products. We cannot imply that any products are ISO registered or certified.